IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL TECHNOLOGIES, INC., *Plaintiff,* *v.* KURIN, INC., *Defendant.*	Civil Action No. 1:19-cv-00097-CFC **JURY TRIAL DEMANDED** **Redacted Version**

DEFENDANT KURIN, INC.'S OPENING BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT (NO. 1) OF INVALIDITY OF U.S. PATENT NO. 9,855,001 DUE TO INDEFINITENESS

Karen I. Boyd (*pro hac vice)*
Jennifer Seraphine (*pro hac vice)*
Louis L. Wai (*pro hac vice)*
Jacob S. Zweig (*pro hac vice)*
Cyndi J. Claxton (*pro hac vice)*
TURNER BOYD LLP
702 Marshall St., Ste. 640
Redwood City, CA 94063
(650) 521-5930
boyd@turnerboyd.com
seraphine@turnerboyd.com
wai@turnerboyd.com
zweig@turnerboyd.com
claxton@turnerboyd.com

Kenneth L. Dorsney (#3726)
Cortlan S. Hitch (#6720)
MORRIS JAMES LLP
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801
(302) 888-6800
kdorsney@morrisjames.com
chitch@morrisjames.com

Jonathan Hangartner (*pro hac vice)*
X-Patents, APC
5670 La Jolla Blvd.
La Jolla, CA 92037
(858) 454-4313
jon@x-patents.com

Dated: May 27, 2021

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Rules

I. NATURE AND STATE OF THE PROCEEDINGS

Plaintiff asserts infringement of U.S. Patent Nos. 9,855,001 ("#001 patent") and 10,039,483 ("#483 patent"). Discovery is closed. No trial date is set.

II. SUMMARY OF ARGUMENT

1. The term "substantial pressure equalization" appears in the two asserted independent claims (1 and 21) of the #001 patent. It is not disputed—and indeed Magnolia's technical expert Dr. Juan Santiago admits—that "substantial pressure equalization" requires "equalization" as between two parts of the claimed blood diversion device. The #001 patent's disclosure does not, however, provide reasonable certainty as to where or how this claim requirement is satisfied, and these claims are therefore invalid due to indefiniteness under 35 U.S.C. § 112.

III. STATEMENT OF FACTS

The relevant facts are set forth in Defendant Kurin, Inc.'s Concise Statement of Facts in Support of Motion for Summary Judgment (No. 1) of Invalidity of U.S. Patent No. 9,855,001 Due to Indefiniteness ("CSOF").

IV. ARGUMENT

A. Legal Standards

1. Summary Judgment

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a

matter of law." Fed. R. Civ. P. 56(a). A court may grant summary judgment based on indefiniteness even when the parties present conflicting expert testimony about whether an artisan of ordinary skill would be able to understand disputed claim terms. *See, e.g.*, *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249-50 (Fed. Cir. 2008) (affirming summary judgment based on intrinsic evidence and noting that conflicting expert testimony does not preclude a finding of indefiniteness).

2. Indefiniteness

Section 112(b) of the Patent Act requires that the claims "particularly point[] out and distinctly claim[] the subject matter which the inventor ... regards as the invention." 35 U.S.C. § 112(b). To satisfy this requirement a claim must be "sufficiently 'definite.'" *Allen Eng'g Cmp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1348 (Fed. Cir. 2002). Definiteness is required "so that interested members of the public, *e.g.*, competitors of the patent owner, can determine whether or not they infringe." *Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1340 (Fed. Cir. 2003). "[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). To comply with § 112, a patent "must provide objective boundaries for those of skill in the

art." *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014) (citing *Nautilus*, 572 U.S. at 911 & n. 8).

Indefiniteness is an issue of law. *Dow Chemical Co. v. Nova Chemicals Corp. (Canada)*, 809 F.3d 1223, 1224-25 (Fed. Cir. 2015).

B. The #001 Patent Fails to Disclose Where or How to Evaluate the "Substantial Pressure Equalization" Claim Limitation

Asserted independent claims 1 and 21 both require "substantial pressure equalization," but neither the claims nor the written description of the #001 patent provide reasonable certainty as to where or how this claim requirement may be satisfied.

Claim 1 of the #001 patent reads:

> An apparatus for obtaining a bodily fluid sample from a patient with reduced contamination, the apparatus comprising:
>
> a reservoir configured to receive an initial volume of bodily fluid withdrawn from the patient; and
>
> a diverter having an inlet, a first outlet in fluid communication with the reservoir, and a second outlet, the inlet configured to be fluidically coupled to the patient, the diverter operable in a first operating mode in which an initial volume of bodily fluid can flow from the inlet to the first outlet, and a second operating mode in which: a) a subsequent volume of bodily fluid can flow from the inlet to the second outlet, and b) the initial volume of bodily fluid is prevented from flowing to the second outlet,
>
> ***the diverter configured to transition from the first operating mode to the second operating mode as a result of the initial volume of bodily fluid flowing from the***

> ***patient and substantial pressure equalization***, thereby sequestering in the reservoir contaminants present in the initial volume of bodily fluid, thereby reducing contamination of the subsequent volume of bodily fluid withdrawn from the patient.

CSOF ¶1. Claim 1 thus requires a diverter operable in two different "operating modes." *Id.* In the first operating mode "an initial volume of bodily fluid" flows from the inlet to a first outlet. *Id.* In the second operating mode "a subsequent volume of bodily fluid" flows from the inlet to a second outlet. *Id.* The diverter must be configured to transition from the first to the second operating mode "***as a result of*** the initial volume of bodily fluid flowing from the patient ***and substantial pressure equalization***." *Id.* (emphasis added).

Asserted claim 21 of the #001 patent also requires a diverter that is configured to divert the flow of bodily fluid as a result of substantial pressure equalization:

> a diverter fluidically coupled to the needle, the diverter including an inlet, a n outlet, and a reservoir configured to receive an initial volume of bodily fluid withdrawn from the patient, the diverter defining a first fluid flow path that allows the initial volume of bodily fluid to flow from the patient until pressure substantially equalizes, and a second fluid flow path that allows a subsequent volume of bodily fluid to flow from the inlet to the outlet after the initial volume of bodily fluid has been sequestered, ***the diverter configured to divert the flow of bodily fluid to the second fluid flow path as a result of receiving the initial volume of bodily fluid from the patient and substantial pressure equalization***, whereby diverting the initial volume of bodily fluid.

CSOF ¶2. This diverter must define two different flow paths: (1) "a first fluid flow path that allows the initial volume of bodily fluid to flow from the patient ***until pressure substantially equalizes***"; and (2) "a second fluid flow path that allows a subsequent volume of bodily fluid to flow from the inlet to the outlet after the initial volume of bodily fluid has been sequestered." *Id.* (emphasis added). As in Claim 1, the diverter of Claim 21 must be configured to divert the flow of bodily fluid to the second fluid flow path "***as a result of*** receiving the initial volume of bodily fluid from the patient ***and substantial pressure equalization."*** *Id.* (emphasis added).

Thus, both claims 1 and 21 require a diverter configured to initially direct blood down one flow path, then transition to direct blood down a different flow path "as a result of" two specific conditions: (i) receiving the "initial volume" of bodily fluid from the patient; and (ii) "substantial pressure equalization." CSOF ¶¶1-2. This "substantial pressure equalization" requires "equalization" as between two parts of the claimed blood diversion device. CSOF ¶¶16-17. Nothing in these claims, however, identities where "substantial pressure equalization" must occur. CSOF ¶¶1-3.

Turning to the written description, the only pressure equalization discussed in the written description of the #001 patent is in connection with "single blood flow path" embodiments, which ***do not include the claimed "diverter***." CSOF

¶¶4-10. This discussion explains only that "pressures equalize" between the lumens of a "first needle" and a "second needle"—elements that are not present in claims 1 and 21. CSOF ¶¶11-13. Asserted claims 1 and 21, in contrast, recite "substantial pressure equalization" in connection with the claimed diverter being "configured to transition from the first operating mode to the second operating mode" (in Claim 1), and "configured to divert" from "the first fluid flow path" to "the second fluid flow path" (in Claim 21), "as a result of … substantial pressure equalization." CSOF ¶¶1-2. Because claims 1 and 21 do not include a "first needle" and "second needle," and because they do not provide with any reasonable certainty where, or between what parts, pressures must "equalize" when those needle elements are not present, these claims are left indefinite. Furthermore, the prosecution history of the #001 patent provides no guidance on this point. CSOF ¶¶14-15.

Thus, neither the claims, the written description, nor the prosecution history provide any guidance, let alone reasonable certainty, as to where or between which parts of the accused device "substantial pressure equalization" must occur. Claims 1 and 21 (and their dependent claims) are therefore invalid for indefiniteness. *See Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, No. CV 15-1168-LPS, 2017 WL 1334733, at *5 (D. Del. Apr. 7, 2017) (citing *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015) (explaining that a claim is indefinite if

the patent does not "convey with reasonable certainty" how to measure a claimed feature)); *see also id.* at *7 n. 15 (citing *Dow Chem. Co.*, 803 F.3d at 634 (finding claim indefinite where different measurement methods gave different results but patent failed to provide guidance on correct method, so a person of skill in the art would not know which test to select)).

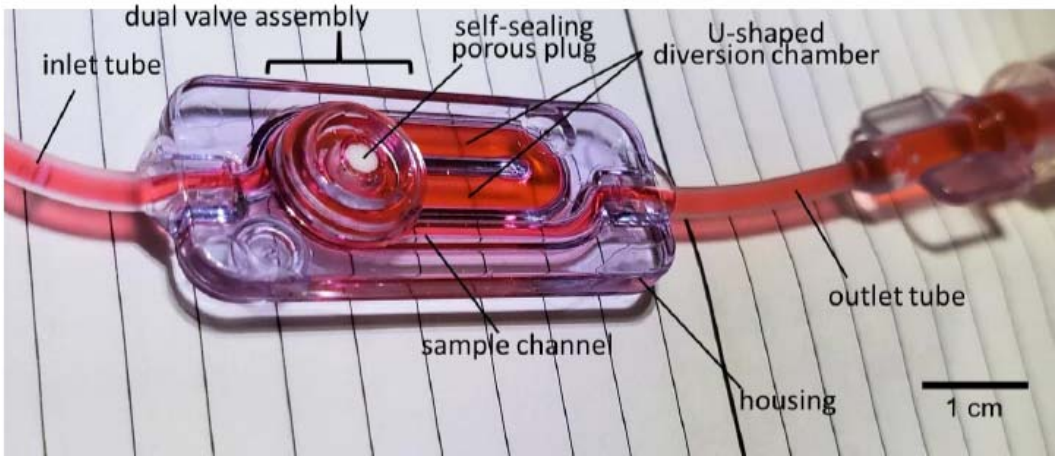
C. Magnolia's Expert's Testimony Confirms that Claims 1 and 21 are Indefinite

There is no dispute that evaluation of the "substantial pressure equalization" claim limitation requires a comparison of the pressure in two or more locations. CSOF ¶¶16-17. Magnolia's expert Dr. Santiago admitted that "pressure differences [are] measured over two places," and agreed that determining "equalization" would require knowing and comparing pressures at "at least two" locations. *Id.* Dr. Santiago further admitted that the written description and asserted claims of the #001 patent do not identify where to measure pressures in order to evaluate this claim limitation. CSOF ¶3; ¶18. Moreover, in deposition, Dr. Santiago could not identify the two locations where pressures must be compared to determine whether "substantial pressure equalization" has occurred "to evaluate claim 1." CSOF ¶19.

When asked directly "where substantial pressure equalization must be determined to evaluate claim 1," Dr. Santiago could not identify specific locations and instead vaguely testified that "one reasonable place to look is in a diverter or in

components that are fluidically coupled to the diverter." *Id.* In fact, Dr. Santiago could not even answer whether the term "substantial pressure equalization" in the #001 patent refers to a *process* where the pressures at two or more locations become more equal over time, or a *state* where the pressures at two or more locations are substantially equal at a single point in time. CSOF ¶20.

Looking at the accused Kurin Lock device, Dr. Santiago has offered a host of potential locations where pressure might be compared. First, in his expert report, he alleges that there is "substantial equalization of liquid pressures ***within the U-shaped diversion chamber***" of the Kurin Lock, but does not identify any particular locations therein. CSOF ¶21 (emphasis added). This "U-shaped diversion chamber" is the large structure identified in Dr. Santiago's annotated photo of the Kurin Lock:



CSOF ¶22.

Later in his report, Dr. Santiago asserts that "***pressure from the blood in the***

U-shaped side channel equalizes with the patient's blood pressure, which causes the second mode of operation where the blood is directed down the sample channel." CSOF ¶23 (emphasis added). Dr. Santiago then asserts that there is "substantial pressure equalization ***between the inlet and the U-shaped diversion chamber***." CSOF ¶24 (emphasis added). In his rebuttal expert report on invalidity, Dr. Santiago identifies a fourth, even more vague possibility, referring to substantial pressure equalization that occurs "***in the Kurin Lock device relative to the pressure in the patient's vein***." CSOF ¶25 (emphasis added).

Dr. Santiago further testified that "substantial pressure equalization" could be considered at a variety of different locations to evaluate the "substantial pressure equalization" requirement, including:

- between "[t]wo points within the U tube structure" of the Kurin Lock, CSOF ¶26, and that this is just "one example," *id.*; or
- between "say, halfway between the 180-degree turn and the dual valve assembly" and "another point in the same horizontal line in the center of the U tube channel on the far side of the 180-degree turn," CSOF ¶27; or
- at "[t]wo other points within the U structure," CSOF ¶28; or
- "you could look at other locations" including points outside the U structure such as the "inlet," CSOF ¶29.

Thus, according to Dr. Santiago, "substantial pressure equalization" could be evaluated virtually anywhere in the accused device, or even between various points within it and outside of it. Ultimately, when asked to identify "any locations within the Kurin Lock that you could compare pressure, and if you found

substantially equal pressure, it ***wouldn't*** satisfy this claim," Dr. Santiago first speculated regarding additional possible locations to compare pressure, and then replied that he would not "exclude any other points." CSOF ¶30 (emphasis added).

Moreover, in discussing this claim element, Dr. Santiago has testified that the pressures at two locations in the device will change over time. CSOF ¶31. According to Dr. Santiago, pressures will "progressively increase," "progressively decrease," and "eventually equalize" at different times and at different points within the Kurin Lock and outside of it (e.g., a patient's "venal pressure"), and that the occurrence of these events could be affected by variables such as "air-to-liquid capillary pressure difference," "hydrostatic pressure difference," and "gravity." CSOF ¶¶31-32; *see Am. Axle & Mfg.*, 2017 WL 1334733, at *6 (discussing indefiniteness where experts agree that multiple variables must be considered, but patent fails to describe appropriate conditions for measuring the claimed features).

Dr. Santiago's testimony further proves the indefiniteness of these patent claims. Dr. Santiago's inability to identify where "substantial pressure equalization" must be evaluated in the Kurin Lock shows that one of skill in the art would not be able to determine the bounds of the asserted claims. *See Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1354 (Fed. Cir. 2005), *abrogated by Nautilus*, 572 U.S. 898 (2014) (finding that inability of the expert to use the parameters he identified to evaluate infringement militates against the

reasonableness of those parameters in determining the scope of the invention).

There is no dispute of material fact that the #001 patent does not disclose (CSOF ¶¶1-15), and one skilled in the art would not know (CSOF ¶¶16-32), which pressures to evaluate to determine whether there has been "substantial pressure equalization" in claims 1 and 21. Thus, summary judgment is appropriate. *See Univ. of Massachusetts v. L'Oreal USA, Inc.*, No. CV 17-0868-CFC-SRF, 2021 WL 1550266, at *2, 6 (D. Del. Apr. 20, 2021) (granting summary judgment of indefiniteness and noting it is proper to do so despite conflicting expert testimony); *Am. Axle & Mfg.*, 2017 WL 1334733, at *5-7 (holding claim terms indefinite "because the claims and the specification fail to provide any guidance about the testing and calculation methods that should be performed to determine whether a system practices these claim elements").

Asserted dependent claims 4, 22-23 and 26-28 are also indefinite, because they depend from claims 1 and 21, respectively. *See Univ. of Massachusetts*, 2021 WL 1550266, at *6.

V. CONCLUSION

Kurin respectfully requests that the Court grant summary judgment that independent claims 1 and 21 of the #001 patent, and dependent claims 4, 22-23 and 26-28, are indefinite because the claim term "substantial pressure equalization"

lacks "objective boundaries for those of skill in the art." *See Interval Licensing*, 766 F.3d 1364.

Dated: May 27, 2021

/s/ Kenneth L. Dorsney

Kenneth L. Dorsney (#3726)
Cortlan S. Hitch (#6720)
MORRIS JAMES LLP
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801
(302) 888-6800
kdorsney@morrisjames.com
chitch@morrisjames.com

Karen I. Boyd
Jennifer Seraphine
Louis L. Wai
Jacob S. Zweig
Cyndi J. Claxton
TURNER BOYD LLP
702 Marshall St., Ste. 640
Redwood City, CA 94063
(650) 521-5930
boyd@turnerboyd.com
seraphine@turnerboyd.com
wai@turnerboyd.com
zweig@turnerboyd.com
claxton@turnerboyd.com

Jonathan Hangartner
X-Patents, APC
5670 La Jolla Blvd.
La Jolla, CA 92037
(858) 454-4313
jon@x-patents.com

Attorneys for Defendant-Counterclaim- Plaintiff Kurin, Inc.

CERTIFICATION BY COUNSEL

The foregoing document complies with the type-volume limitation of the parties' Scheduling Order, D.I. 24, dated June 20, 2019 and this Court's March 2, 2020 form Scheduling Order For All Cases where Infringement is Alleged. The text of this brief, including footnotes was prepared in Times New Roman, 14-point. According to the word processing system used to prepare it, the brief contains 2,551 words, excluding the case caption, signature block, table of contents and table of authorities.

Dated: May 27, 2021

/s/ Kenneth L. Dorsney
Kenneth L. Dorsney (#3726)

CERTIFICATE OF SERVICE

I, Kenneth L. Dorsney, hereby certify that on May 27, 2021, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed.

I further certify that on the same date the attached document was electronically mailed to the following person(s):

Rodger Dallery Smith, II
Anthony David Raucci
MORRIS, NICHOLS, ARSHT & TUNNELL LLP
1201 North Market Street
Wilmington, DE 19899
rsmith@morrisnichols.com
Araucci@morrisnichols.com

Attorneys for Plaintiff

David J. Lisson
Micah G. Block
Philip T. Sheng
Kathryn Bi
Ian Hogg
Ashok Ramani
DAVIS POLK & WARDELL LLP
1600 El Camino Real
Menlo Park, CA 94025
david.lisson@davispolk.com
micah.block@davispolk.com
Philip.sheng@davispolk.com
Kathryn.bi@davispolk.com
ian.hogg@davispolk.com
ashok.ramani@davispolk.com
dpw.service.mmt@davispolk.com

Attorneys for Plaintiff

Dated: May 27, 2021

/s/ Kenneth L. Dorsney
Kenneth L. Dorsney (#3726)
Cortlan S. Hitch (#6720)
MORRIS JAMES LLP
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801
(302) 888-6800
kdorsney@morrisjames.com
chitch@morrisjames.com

Attorneys for Defendant Kurin, Inc.